IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., and ANDRX LABS, L.L.C.,	)	
Plaintiff,	)	C.A. No. 09-37-JJF
v.	)	**JURY TRIAL DEMANDED**
LUPIN LTD., and LUPIN PHARMACEUTICALS, INC.,	)	
Defendant.	)	

DEFENDANTS' ANSWER

The Defendants, Lupin Pharmaceuticals, Inc., ("Lupin Pharma") and Lupin Limited ("Lupin Ltd.") (collectively the "Lupin Defendants") by and through their attorneys, respond to each of the numbered paragraphs to the Complaint filed against them by the Plaintiffs, Sciele Pharma, Inc., Andrx Corporation, Andrx Pharmaceuticals, Inc. (N/K/A Watson Laboratories, Inc.-Florida), Andrx Pharmaceuticals, L.L.C., Andrx Labs, L.L.C., Andrx Laboratories (NJ), Inc., and Andrx EU Ltd. ("the Plaintiffs") as follows:

THE PARTIES

1. On information and belief, the Lupin Defendants admit the allegations set forth in paragraph 1 of the Complaint.

2. On information and belief, the Lupin Defendants admit the allegations set forth in paragraph 2 of the Complaint.

3. The Lupin Defendants admit that Lupin Pharma is a Virginia corporation and a wholly-owned subsidiary of Lupin Ltd. and that it has a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, 21202. Lupin Pharma further admits that it distributes generic drugs for sale and use throughout the United States, including in this judicial district. The Lupin Defendants deny the remaining allegations made in paragraph 3 of the Complaint.

4. The Lupin Defendants admit that Lupin Ltd. is a corporation organized and existing under the laws of India, with a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India, and with its only places of business located in India; that Lupin Ltd. develops, manufactures, markets and sells pharmaceutical products, including generic pharmaceutical products; and that Lupin Pharma distributes pharmaceutical products, including generic pharmaceutical products manufactured by Lupin Ltd. that have been authorized by the United States Food and Drug Administration under applicable law. The Lupin Defendants deny the remaining allegations made in paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. The Lupin Defendants admit that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§1331 and 1338(a). Lupin Ltd. denies that venue is proper as to it in this District. Lupin Pharma admits that venue is proper as to it in this District.

6. Lupin Ltd. denies that personal jurisdiction in this District exists as to it in this action. The Lupin Defendants further aver that they informed Plaintiffs, through counsel and prior to the filing of any Complaint by the Plaintiffs, that they would not contest personal jurisdiction or venue in the District of Maryland, and that they would not agree that jurisdiction

exists or that venue is proper as to Lupin Ltd. in this District. The Lupin Defendants deny the remaining allegations made in paragraph 6 of the Complaint.

7. The Lupin Defendants admit that included in ANDA No. 90-692 is a letter from Lupin Ltd. that identifies an employee of Lupin Pharmaceuticals, Inc., as "the United States Agent of Lupin Limited for [this] ANDA." The Lupin Defendants admit that Lupin Pharma participated in the filing of ANDA No. 90-692. The Lupin Defendants deny the remaining allegations made in paragraph 7 of the Complaint.

8. The Lupin Defendants admit that Lupin Ltd. develops, manufactures, markets and sells pharmaceutical products, including generic pharmaceutical products; that Lupin Pharma distributes pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Lupin Ltd. that have been authorized by the United States Food and Drug Administration under applicable law; that Lupin Ltd. maintains a website at www.lupinworld.com; and that Lupin Pharma has its offices at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. The Lupin Defendants deny the remaining allegations made in paragraph 8 of the Complaint.

9. The Lupin Defendants deny the allegations made in paragraph 9 of the Complaint.

10. The Lupin Defendants admit that Lupin Pharma has a distribution network in the United States and that Lupin Pharma has formed marketing alliances with other companies in the United States. The Lupin Defendants deny the remaining allegations made in paragraph 10 of the Complaint.

11. The Lupin Defendants admit that Lupin Pharma's website reflects that Amerisource Bergen, Cardinal Health and Walgreens, as well as others, are authorized

distributors of record. http://www.lupinpharmaceuticals.com/adrsub.htm#product_a. The Lupin Defendants deny the remaining allegations made in paragraph 11 of the Complaint.

12. The Lupin Defendants admit that the website for Lupin Pharma reflects that Happy Harry's, at 326 Ruthar Drive, in Newark, Delaware, is an authorized distributor for Lupin Pharma, and that the page of Lupin Pharma's website that contains this information bears a copyright date of 2006. http://www.lupinpharmaceuticals.com/ adrsub.htm#product_h The Lupin Defendants admit that, according to a Walgreen's website, Happy Harry's is a Walgreen's Pharmacy, and that the website claims that, prior to 1987, Happy Harry's was "Delaware's largest drug store chain." http://www.walgreens.com/about/company history/happy.jsp. The Lupin Defendants deny the remaining allegations made in paragraph 12 of the Complaint. .

13. The Lupin Defendants admit that Lupin Ltd. manufactures Suprax®, that Lupin Pharma distributes Suprax® in the United States; and that Suprax® is sold in the United States.. The Lupin Defendants admit that the Suprax® package insert states that Suprax® is "Manufactured for:" Lupin Pharmaceuticals, Inc. The Lupin Defendants deny the remaining allegations made in paragraph 13 of the Complaint.

14. The Lupin Defendants admit that Lupin Pharma has entered into a multi-year agreement for the AeroChamber Plus® line of products with Forest Laboratories, Inc., and that Lupin Pharma has agreed to use its 50 person sales force to promote this Forest Labs product to pediatricians in the United States. Upon information and belief, the Lupin Defendants admit that Forest Labs' AeroChamber Plus® line of products is distributed throughout the United States. The Lupin Defendants deny the remaining allegations made in paragraph 14 of the Complaint.

15. Lupin Pharma admits that this court has personal jurisdiction over it. The Lupin Defendants deny the remaining allegations made in paragraph 15 of this Complaint..

16. Lupin Ltd. denies that personal jurisdiction exists and denies that venue is proper as to it for this case in this District. The Lupin Defendants deny the remaining allegations made in paragraph 16 of the Complaint.

PATENTS IN SUIT

17. The Lupin Defendants admit that United States Patent No. 6,099,859 ("the '859 patent"), titled "Controlled Release Oral Tablet Having A Unitary Core," was issued by the United States Patent and Trademark Office ("PTO"), that the issue date set forth on the face of the '859 patent is August 8, 2000; that the assignee on the face of the '859 patent is Andrx Pharmaceuticals, Inc.; and that the Compliant purports to attach a copy of the '859 patent, as Exhibit A. The Lupin Defendants deny that the '859 patent was "duly and legally" issued by the PTO. The Lupin Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations made in paragraph 17 of the Complaint, and, therefore, deny them.

18. The Lupin Defendants admit that United States Patent No. 6,866,866 ("the '866 patent"), titled "Controlled Release Metformin Compositions," was issued by the United States Patent and Trademark Office ("PTO"), that the issue date set forth on the face of the '866 patent is March 15, 2005; that the assignee on the face of the '866 patent is Andrx Labs, LLC; and that the Complaint purports to attach a copy of the '866 patent, as Exhibit B. The Lupin Defendants deny that the '866 patent was "duly and legally" issued by the PTO. The Lupin Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations made in paragraph 18 of the Complaint, and, therefore, deny them.

ACTS GIVING RISE TO THIS ACTION

19. Upon information and belief, the Lupin Defendants admit that Andrx Labs, LLC is listed by the FDA as the holder of New Drug Application ("NDA") No. 21-574 for Fortamet® brand metformin hydrochloride extended release tablets. Upon information and belief, the Lupin Defendants aver that the '859 and '866 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Fortamet®, together with United States Patents No. 6,495,162 and 6,790,459. The Lupin Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations made in paragraph 19 of the Complaint, and, therefore, deny them.

20. The Lupin Defendants admit that ANDA No. 90-692 was submitted by Lupin Ltd. to the FDA under §505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), and that ANDA No. 90-692 seeks FDA approval for the commercial manufacture, use and sale of generic extended release tablet products containing 500 milligrams and 1000 milligrams of metformin hydrochloride ("the ANDA Products"). The Lupin Defendants admit that ANDA No. 90-692 seeks to market the ANDA Products prior to the expiration of the '859 and '866 patents, and that the ANDA contained a certification with respect to those patents, and with respect to United States Patents No. 6,495,162 and 6,790,459. The Lupin Defendants deny the remaining allegations made in paragraph 20 of the Complaint.

21. The Lupin Defendants admit that on or about December 3, 2008, pursuant to §505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin Ltd. sent a statement pursuant to §505(j)(2)(A)(vii)(IV) statement (the "Notice Letter") to Watson Pharmaceuticals and Andrx, in which Lupin Ltd. represented that it had filed ANDA No. 90-692, seeking to market the ANDA Products prior to the expiration of the '859 and '866 patents, and that its

ANDA contained a certification with respect to those patents, and with respect to United States Patents No. 6,495,162 and 6,790,459. The Lupin Defendants deny that the remaining allegations set forth in paragraph 21 of the Complaint.

FIRST COUNT (UNITED STATES PATENT No. 6,099,859)

22. The Lupin Defendants incorporate herein their answers to the allegations made in paragraphs 1 through 21 of the Complaint, as if those answers had been realleged and set forth again in full.

23. The Lupin Defendants deny the allegations made in paragraph 23 of the Complaint.

24. The Lupin Defendants deny the allegations made in paragraph 24 of the Complaint.

25. Lupin Ltd. and Lupin Pharma admit that they were aware of the '859 patent. The Lupin Defendants deny the remaining allegations made in paragraph 25 of the Complaint.

26. The Lupin Defendants deny the allegations made in paragraph 26 of the Complaint.

SECOND COUNT (UNITED STATES PATENT No. 6,866,866)

27. The Lupin Defendants incorporate herein their answers to the allegations made in paragraphs 1 through 26 of the Complaint, as if those answers had been realleged and set forth again in full.

28. The Lupin Defendants deny the allegations made in paragraph 28 of the Complaint.

29. The Lupin Defendants deny the allegations made in paragraph 29 of the Complaint.

30. The Lupin Defendants admit that they were aware of the '866 patent. The Lupin Defendants deny the remaining allegations made in paragraph 30 of the Complaint.

31. The Lupin Defendants deny the allegations made in paragraph 31 of the Complaint.

THIRD COUNT (LUPIN PHARMA)

32. Lupin Pharma incorporates herein its answers to the allegations made in paragraphs 1 through 31 of the Complaint, as if those answers had been realleged and set forth again in full. Lupin Ltd. does not respond to the allegations made in paragraph 32 of the Complaint because there are no allegations directed to it.

33. Lupin Pharma admits that it participated in the submission of ANDA No. 90-692 to the FDA, and that, at that time, it was aware of the '859 and '866 patents. Lupin Pharma denies the remaining allegations made in paragraph 33 of the Complaint. Lupin Ltd. does not respond to the allegations made in paragraph 33 of the Complaint because there are no allegations directed to it.

34. Lupin Pharma denies the allegations made in paragraph 34 of the Complaint. Lupin Ltd. does not respond to the allegations made in paragraph 34 of the Complaint because there are no allegations directed to it.

35. The Lupin Defendants further answer that any allegations in the Complaint requiring a response from either or both of them not specifically admitted or denied are denied. The Lupin Defendants also deny that the Plaintiffs are entitled to the judgment and relief prayed for in paragraphs (a) through (e) of the Complaint.

DEFENSES

Further responding to the Complaint, and as additional defenses thereto, the Lupin Defendants assert the following defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on the Plaintiffs.

FIRST DEFENSE
(Non-infringement of the '859 Patent)

36. The manufacture, use, offer for sale, sale, or importation of the ANDA Products does not and will not infringe any claim of the '859 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE
(Invalidity of the '866 Patent)

37. One or more of the claims of the '866 patent, if construed to encompass the ANDA Products, are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example and not of limitation, one or more of the claims of the '866 patent are invalid under 35 U.S.C. §§ 103 and 112.

THIRD DEFENSE
(Non-infringement of the '866 Patent)

38. The manufacture, use, offer for sale, sale, or importation of the ANDA Products does not and will not infringe any claim of the '866 patent, either literally or under the doctrine of equivalents.

FOURTH DEFENSE
(Failure to State a Claim)

39. To the extent that Plaintiffs allege that submission of ANDA 90-692 makes this case exceptional under 35 U.S.C. § 285, the Complaint fails to state a claim upon which relief can be granted and must be dismissed.

FIFTH DEFENSE
(Lack of Personal Jurisdiction)

40. Lupin Ltd. denies that personal jurisdiction exists in this case as to it in this District.

SIXTH DEFENSE
(Improper Venue)

41. Lupin Ltd. denies that venue is proper as to it in this case in this District.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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Dated: February 9, 2009
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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on February 9, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on February 9, 2009, the attached document was Electronically Mailed to the following person(s):

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